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EXAMINER

JOHNSON III, HENRY M

ART UNIT PAPER NUMBER

3739

DATE MAILED: 10/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

DAVID  
Beatty 919-854-1400

# Office Action Summary

Application No.

09/529,210

Applicant(s)

DOUGAL, GORDON REX  
PATERSON

Examiner

Henry M Johnson, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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#### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 3, 2002 has been entered.

#### ***Specification***

The disclosure is objected to because of the following informalities: on page 4, lines 16-19, the period of application is confusing. The examiner believes the microsecond times are intended to be pulse widths or pulse duration. Clarification is required to avoid conflict with the treatment times mentioned later in lines 24-28.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 5-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The term "and" implies both wavelengths are operated simultaneously, a configuration not supported by the disclosure.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1 and 5-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "narrow band" in claim 1 is a relative term which renders the claim indefinite. The term "narrow band" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Regarding claim 1, the phrase "and/or" renders the claim indefinite because the claim must be one or the other, not both, to be definite.

A wavelength range of 980nm to 1300nm is cited in the disclosure. Claim 1 relates this range to a bandwidth, making the claim indefinite.

Regarding claim 12, the claim is not clear whether the microsecond times are for the pulse duration or treatment times.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 6-10, 12, 15-24 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,063,108 to Salansky et al. Salansky et al discloses an apparatus for treating tissue that

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uses radiation in the range of 400-2000nm (Col. 3, line 44) with an intensity of from 0.2 to 5000 mW/cm<sup>2</sup>. The power intensity anticipates the **at least** 50  $\mu\text{W}/\text{cm}^2$  and 500  $\mu\text{W}/\text{cm}^2$ . Salansky et al teaches the full bandwidth should not exceed 30 to 40nm (Col. 16, line 42). The apparatus may use light emitting diodes (Col. 3, line 51) that inherently produce divergent radiation or a laser or laser diode may also be used as the source. Diodes, by definition, include a PN junction. Salansky et al teaches the radiation can be either pulsed or continuous with average powers adjustable by the processor over a wide range by varying the pulse repetition rates over a wide range of hertz and the pulse durations from nanoseconds to milliseconds (Col 14, line 31). The treatments disclosed by Salansky et al, provide exposure times from 3 to 500 seconds (Table 8) and dosages in Joules/ cm<sup>2</sup> (Table 5) as is common in the art. A central processor is disclosed that stores the selected parameters for operating the apparatus to meet specific treatment protocols (Col. 21, lines 40-44) and effectively limit the radiation to specific ranges. A display shows system parameters such as timer, power, and frequency (Col. 23, line 24). Salansky et al teaches treating numerous afflictions including herpes (Col. 37, line 17). Figure 13 shows a flexible applicator that can be wrapped around the surface contours of the body (Col. 26, line 1) that provides the means of reducing all ambient light.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,063,108 to Salansky et al. Salansky et al does not disclose expressly the specific divergence of the emitting device. Applicant has not disclosed that the increased beam divergence provides any advantage or unexpected result. Light emitting diodes are commercially available with a wide range of divergent specifications.

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Therefore, pending a statement of criticality, the cited divergence is considered to be an obvious design choice to one having ordinary skill in the art.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,063,108 to Salansky et al. Salansky et al does not teach a specific average power, but does teach that average power is less than peak power (Col. 6, line 41) and may be changed by varying the pulse repetition rate and pulse duration (Col. 14, lines 29-33). It would have been obvious to one having ordinary skill in the art to manipulate the pulse and repetition rate to obtain the desired average power.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,063,108 to Salansky et al. Salansky et al cites repetition frequencies from 0 to 200 Hz and 1000 to 10,000 Hz, yet does not disclose 201 to 999 Hz specifically. Applicant has not disclosed that the specific repetition rate provides any advantage or unexpected result. Salansky et al teaches treatment routines for many different afflictions that are programmed as protocols into the processor that controls the frequency, pulse width and repetition rate. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The cited frequency/repetition rate is considered to be an obvious design choice to one having ordinary skill in the art.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,063,108 to Salansky et al in view of Lasers and Electro-Optics by Christopher C. Davis, Cambridge University Press 1996, page 289. Salansky et al does not specifically disclose a diode with multiple PN junctions. The use of multiple PN junctions is old and well known in the art of LED construction as disclosed by Lasers and Electro-Optics by Christopher C. Davis, thereby making their use an obvious design choice.

### ***Response to Arguments***

MPEP § 2131.03 states "PRIOR ART WHICH TEACHES A RANGE WITHIN, OVERLAPPING, OR TOUCHING THE CLAIMED RANGE ANTICIPATES IF THE PRIOR ART RANGE DISCLOSES THE CLAIMED RANGE WITH "SUFFICIENT SPECIFICITY". What constitutes a "sufficient specificity" is fact dependent. If the claims are directed to a narrow range, the reference teaches a broad range, and there

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is evidence of unexpected results within the claimed narrow range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims".

The apparatus of Salansky et al is disclosed and capable of operation at the wavelengths of the claims using commercially available emitters. Salansky et al in treating herpes using a wavelength of 660 nm, achieved relief and dryness of lesions in 1-2 days (Col. 38, line 4). This is less time than the 3 days cited in the instant application using 1072 nm. Also, the transmittance data shows that 660 nm has a higher water transmittance than 1072 nm, thus is if transmittance of water is a primary factor, 660 nm should be more effective. The conclusion is that no unexpected results have been established. Further, Grove et al (U.S. Patent 5,527,350) discloses the absorption coefficient of water is lowest (highest transmittance) under 1100 nm and lowest under 700 nm (Fig. 2) further substantiating the 660 nm wavelength as potentially more effective based on water transmittance.

The argument regarding restricting the total bandwidth to simulate the transmission spectrum of water is not understood. The range of 980 nm to 1300 nm has neither the highest nor lowest transmissivity; only two peaks within the range. Further, if this is a total bandwidth, the center would be at 1140 nm which appears to have no particular significance. In light of the Salansky et al results cited above, the argument is not persuasive.

Salansky et al indeed teaches a bandwidth not to exceed 30-40 nm. Since "narrow band" is a relative term, and lacking a definition thereof, the bandwidth of Salansky et al is considered narrow.

Regarding the divergence having a critical role, stating that it **may** provide a safety aspect or **may** avoid hot spots is not sufficient to establish critically.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M Johnson, III whose telephone number is (703) 305-0910. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Henry M. Johnson, III  
Examiner  
Art Unit 3739

Hmj  
October 28, 2002

A handwritten signature in black ink, appearing to read 'Lee Cohen', with a long horizontal flourish extending to the right.

Lee Cohen  
Primary Examiner